

FORM PTO-1449 (Modified)

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S
INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

ATTY. DOCKET NO.
02940086PASERIAL NO.
09/944,221APPLICANT:
J. Peart, et al.FILING DATE:
September 4, 2001GROUP:
1617

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

EXAMINER INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPRO.)
JHNA	5,492,688	02/20/96	P. Byron, et al.			3/23/94
	5,736,124	4/7/98	R. Akehurst, et al.			05/30/95
	5,916,540	6/29/99	R. Akehurst, et al.			4/6/98
JHNA	5,922,306	7/13/99	R. Akehurst, et al.			4/15/98

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

Not provided		T. Tzou. DENSITY, EXCESS MOLAR VOLUME, AND VAPOR PRESSURE OF PROPELLANT MIXTURES IN METERED-DOSE INHALERS: DEVIATION FROM IDEAL MIXTURES: T. Tzou: Respiratory Drug Delivery. VI, 1998 439-443
		J. H. Bell, et al.: Variation in delivery of isoprenaline from various pressurized inhalers. J. Pharm Pharmac. 1973, Suppl. 32P-36P
JHNA		F. Moren: Drug Deposition of pressurized inhalation aerosols Influence of vapour pressure and metered volume; Int'l Journal of Pharmaceuticals. 1 (1978) 213-218

EXAMINER

DATE CONSIDERED

12/17/05

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

-FORM PTO-1449 (Modified)

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S
INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

ATTY. DOCKET NO.
98-70

SERIAL NO. 09/944 221

APPLICANT:
J. Pearl, et al.

FILING DATE: 9-4-01

GROUP:

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

EXAMINER INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPRO.)

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

JHAA	Long-Term Efficacy and Safety of Dronabinol for Acquired Immunodeficiency Syndrome-Associated Anorexia, Journal of Pain and Symptom Management; Vol. 14 No. 1 July 1997 pgs 7-14
	Dronabinol as a Treatment for Anorexia Associated with Weight Loss in Patients with AIDS; Journal of Pain and Symptom Management; Vol. 10 No. 2; February 1995; pgs 89-97
	Efficacy of tetrahydrocannabinol in patients refractory to standard antiemetic therapy; Investigational New Drugs 6:243-246; (1988); Mary McCabe, Frederick P. Smith, John S. Macdonald, Paul V. Woolley, Deborah Goldberg, and Philip S. Schien; Divisional of Medical Oncology, Vincent T. Lombardi Cancer Research Center, Dept. of Medicine, Georgetown University
	Tetrahydrocannabinol for Refractory Vomiting Induced by Cancer Chemotherapy; JAMA March 28, 1980-Vol 243, No. 12
	ANTIEMETICS-SALLAN, ET AL. The New England Journal of Medicine; Jan. 17, 1980; Vol 302 No. 3; pgs 135-138
	Delta-9-Tetrahydrocannabinol as an Antiemetic for Patients Receiving Cancer Chemotherapy; December 1979; Annals of Internal Medicine; Vol 91 No. 6; pgs. 825-830
	Delta-9-Tetrahydrocannabinol as an Antiemetic in Cancer Patients Receiving High-Dose Methotrexate; December 1979; Annals of Internal Medicine; Vol. 91 No. 6; pgs. 820-824
	Analgesic effect of Delta-9-tetrahydrocannabinol; Dept. of Psychiatry and Internal Medicine, University of Iowa College; Feb-March 1975; pgs. 139-143
	Analgesic Properties of delta-9-tetrahydrocannabinol and codeine; Depart., of Psychiatry and Medicine, University of Iowa; published March 29, 1975; pgs 84-89
	The effect of orally and rectally administered 9-tetrahydrocannabinol on spasticity: A pilot study with 2 patients; Institute of Pharmacy, University of Bern; International Journal of Clinical Pharmacology and Therapeutics, Vol 34 No. 10-1996 (446-452)
JHAA	Delta-9-THC in the Treatment of Spasticity Associated with Multiple Sclerosis; Dept. of Psychiatry at U.C.L.A.; 1988 Hawthorne Press; pgs. 39-50.
	Tetrahydrocannabinol for Tremor in Multiple Sclerosis, David Clifford, MD, Division of Clinical Neuropharmacology and Dept. of Neurology and Neurological Surgery Washington School of Medicine, Published December 12, 1982; Annals of Neurology Vol 13 No. 6 June 1983; pgs 669-671
	Treatment of Human Spasticity with 9-Tetrahydrocannabinol; J. Clin Pharmacol. 1981;21:413S-416S
	Delta-9-tetrahydrocannabinol shows antispastic and analgesic effects in a single case double blind trial; Eur Arch Psychiatry Clin Neurosci 1990;240(1):1-4
	Effect of Marijuana on Intraocular and Blood Pressure in Glaucoma; American Academy of Ophthalmology; March 1980 Vol. 87 Number 3; pgs. 222-228
	Effect of Delta-9-Tetrahydrocannabinol on Intraocular Pressure in Humans; August 1977; Southern Medical Journal Vol. 70 No. 8; pgs. 951-954
	ANTIEMETIC EFFECT OF Delta-9 Tetrahydrocannabinol in patients receiving Cancer Chemotherapy; New England Journal of Medicine; October 16, 1975, Vol. 293 No. 16 pgs. 795-797

Not provided or found in records of parent case

12/17/05

<i>JHAA</i>		Comparison of Ozone Size Distributions from Pressurized Aerosols Formulations or Suspensions; Pharmaceutical Research Vol. 5 No. 1, 1988, Plenum Publishing Corp. pgs. 36-39
<i>JHAA</i>		Changing to CFC-Free Inhalers: The Technical and Clinical challenges; The Pharmaceutical Journal Vol. 259; November 29, 1997; pgs 896-898
<i>JHAA</i>		Drug-surfactant-propellant interactions in HFA-formulations; International Journal of Pharmaceutics; 186 (1999) 13-30
<i>JHAA</i>		Drug form Selection in Albuterol-containing Metered-Dose Inhaler Formulations and its Impact on Chemical and Physical Stability; Journal of Pharmaceutics Sciences; Vol 86 No. 12, December 1997 pgs. 1352-1357
<i>JHAA</i>		The Identification, isolation, and preservation of 9-tetrahydrocannabinol Detp. Of Toxicology, Indiana University Med. Ctr., J. Pharm. 1971, 23, 190-195
<i>JHAA</i>		Stability of Tetrahydrocannabinols I J. Pharmaceutics Sciences Vol. 63, No. 10., October 1974; pgs. 1563-1574

EXAMINER

DATE CONSIDERED

12/17/05

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

(Use several sheets if necessary)

ATTY DOCKET NO.

' 02940086P.

SERIAL NO.	
------------	--

09/944,221

APPLICANT(S)

J. Peart et al.

FILING DATE

9-4-01

GROUP

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>[Signature]</i>		Ross, S., et al.; Constituents of Cannabis Sativa L. XXXVIII; A Review of the Natural Constituents: 1980-1994; Zagazig J Pharm Sci, December, 1995; Vol. 4, No. 2, pp. 1-10.
		Tashkin, DP, et al., Subacute Effects of Heavy Marihuana Smoking on Pulmonary Function in Healthy Men; New Eng. J of Med. 294:125-129, January 15, 1976.
		Turner, et al., Constituents of Cannabis sativa L. XVIII - Electron Voltage Selected Ion Monitoring Study of Cannabinoids; Biomedical Mass Spectrometry, Vol., 7, No. 6, 1990 pp. 247-256.
<i>[Signature]</i>		Maurer et al.; Delta9 tetrahydrocannabinol Shows Antispastic and Analgesic Effects in a Single Case Double-blind Trial; Eur Arch Psychiatry Clin Neurosci 240:1-4, 1990.

EXAMINER

DATE CONSIDERED

12/17/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

-FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	ATTY. DOCKET NO. 98-70	SERIAL NO. 09844221
	APPLICANT: J. Peart, et al.	
	FILING DATE: 9-4-01	GROUP:

REFERENCE DESIGNATION

U.S. PATENT DOCUMENTS

EXAMINER INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPRO.)

FOREIGN PATENT DOCUMENTS


	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

Not provided	Asgharian, B., Wood, r. & Schlesinger, R.B. (1995). Empirical modeling of particle deposition in the alveolar region of the lungs: A basis for interspecies extrapolation. Fund Appl toxicol, 27, 232-238.
	Barnett, C., Chiang, C., Perez-Reyes, M. & Owens, S. (1982). Kinetic study of smoking marijuana. J. Pharmacokin Biopharm, 10, 495-506
	Byron, P.R. (1994) Dosing reproducibility from experimental albuterol suspension metered-dose inhalers. Pharm Res, 11, 580-4.
	Chiang, C.W. & Barnett, G. (1984). Marijuana effect and delta-9-tetrahydrocannabinol plasma level. Clin Pharmacol Ther, 36-234-238.
	Christensen, H.d., Freudenthal, R.I., Gidley, J.T., Rosenfeld, R., Boegh, G., Testino, L., Brine, D.R., Pin, C.G., & Wall, M.E. (1971) Activity of Delta8-and Delta-9-tetrahydrocannabinol and related compounds in the mouse. Science, 172, 165-167
	Compton, D., Aceto, M., Lowe, J. & Martin, B. (1996) In vivo characterization of a specific cannabinoid receptor antagonist (SR141716A): inhibition of delta 9-tetrahydrocannabinol-induced responses and apparent agonist activity. J. Pharmacol Exp. Ther. 277,586-594.
	Compton, D.R., Rice, K.C., De Costa, B.R., Razdan, R.K., Melvin, L.S., Johnson, M.R. & Marin, B.R. (1993). Cannabinoid structure-activity relationships: Correlation of receptor binding and in vivo activities. J. Pharmacol Exp Ther, 265, 218-226.
	Cone, E. & Huestis, M., (1993). Relating blood concentrations of tetrahydrocannabinol and metabolites to pharmacologic effects and time of marihuana usage. Ther Drug Mon, 15, 527-532.
	D'Amour, F.E. & Smith, D.L. (1941) A method for determining loss of pain sensation. J. Pharm Exp Ther, 72, 74-79
	Ford, R.D., Balster, R.L., Dewey, W.L., & Beckner, J.S., (1977). Delta 9-THC and 11-OH-delta 9-THC: Behavioral effects and relationship to plasma and brain levels. Life Sci., 20, 1993-2000-4.
	Gill, E. W. & Jones, J. (1972) Brain levels of delta 1-tetrahydrocannabinol and its metabolites in mice-correlation with behavior, and the effect of the metabolic inhibitors SKF 525A and piperonyl butoxide. Biochem. Pharmacol., 21, 2237-2248.
	Gupta, P.K. & Hickey, A. J. (1991). Contemporay approaches in aerosolized drug delivery to the lungs. J. Controlled release, 17, 129-148.
	Henderson, R., Tennant, F., & Guernsey, R. (1972) Respiratory manifestations of hashish smoking. Arch Otol, 95, 248-251.
	Hiller, F.C., Wison, F.J.J., Mazumder, M.K., Wison, J.D. & Bone, R.C., (1984) Concentration and particle size distribution in smoke from marijuana cigarettes with different delta 9-tetrahydrocannabinol content. Fundam Appl Toxicol, 4,451-454.
	House-of-Lords-Select-Committee-on-Science-and-Technology (1998). Ninth Report. Cnnabis: The Scientific and Medical Evidence.
	Huber, G.L., Simmons, G.A., McCarthy, C.R., Cutting, MB., Laguarda, R. & Pereira, W. (1975) Depressant effect of marijuana smoke on antibactericidal activity of pulmonary alveolar macrophages. Chest, 68, 769-73.
	Huestis, M.A., Sampson, A.H., Holicky, B.J., Henningfield, J.E. & Cone, E.J. (1992) Characterization of the absorption phase of marijuana smoking. Clin Pharmacol Ther, 52, 31-41.
Not provided	Johnson, E., Ohlsson, A., Lindgren, J.E., Agurell, S., Gillespies, H. & Hollister, L. E. (1987) Single dose kinetics of deuterium-labelled cannabiniol in man after intravenous admistration and smoking. Biomed Environ Mass Spectrum, 14, 495-499

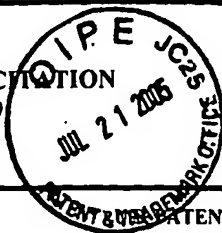
[Signature]

12/13/05

JHAA		Lichtman, A.H., Pearl, J.L., Bridgen, D.T., Razdan, R.K., Wilson, D.M., Poklis, Y., Byron, P.R. & Martin, B.R. (2000) Pharmacological evaluation of aerosolized cannabinoids in mice. Eur J. Pharmacol, 399, 11-149.
		Lichtman, A.H., Poklis, J.L., Poklis, A., Wilson, D.M. & Martin, B.R. (2001) The pharmacological activity of inhalation exposure to marijuana smoke in mice. Drug Alc Depend 63, 107-116.
		Little, P.J., Compton, D.r., Johnson, MR., Melvin, L.S. & Martin, B.R. (1988) Pharmacology and stereoselectivity of structurally novel cannabinoids in mice. J. Pharmacol Exp Ther, 247, 745-747.
		Mattes, R.D., Shaw, L.M., Edling-Owens, J., Engleman, K. & Elsohly, M.A. (1993) Bypassing the first-pass effect for the therapeutic use of cannabinoids. Pharmacol Biochem Behav, 44, 745-747
		Matthias, P., Tashkin, DP., Marques-Magallanes, J.A., Wilkins, J.N. & Simons, M.S. (1997) Effects of Varying Marijuana Potency on Deposition of Tar and Delta 9-THC in the Lung During Smoking. Pharmacol Biochem Behav. 58, 1145-1150.
		Ohlsson, A., Lindgren, J.E., Wahleim, A., Agurell, S., Hollister, L. E. & Gillespie, H.K. (1980) Plasma delta-9 tetrahydrocannabinol concentrations and clinical effects after oral and intravenous administration and smoking. Clin Pharmacol Ther, 28, 409-16.
JHAA		Ohlsson, A., M. Widman, M., Carlsson, S., Ryman, I., & Strid, C. (1980) Plasma and brain levels of delta 6-THC and seven monooxygenated metabolites correlated to the cataleptic effect in the mouse. Acta Pharmacol. Et Toxicol., 47, 308-317
Not provided		Perlin, E., Smith, C.G., Nichols, A.I., Almirez, r., Flora, K.P., Craddock, J.C. & Peck, C.C. (1985) Disposition and bioavailability of various formulations of tetrahydrocannabinol in the rhesus monkey. J. Pharm Sci, 74, 171-174.
JHAA		rinaldi-Carmona, M., Barth, F., Heaulme, M., Shire, D., Calandra, B., Congy, C., Martinez, S., Maruani, J., Neliat, G., Caput, D., Ferrara, P., Soubrie, P., Breliere, J.C., & Lefur, G. (1994) SR141716A, a potent and selective antagonist of the brain cannabinoid receptor. GEBS Lett, 350, 240-244
JHAA		Schlesinger, R.B. (1985) Comparative deposition of inhaled aerosols in experimental animals and humans a review. J. Toxicol Environ Health, 15, 197-214
Not provided		USP (2000) Physical Tests and Determinations <601> Aerosols, metered-dose inhalers, and dry powder inhalers. In United States Pharmacopeia (USP 24) PP. 1895-1912. Philadelphia, PA: National Publishing
JHAA		Vachon, L., Robins, A. & Gaensler, E.A. (1976) Airways response to aerosolized delta 9-tetrahydrocannabinol: preliminary report. In The Therapeutic potential of marijuana. Ed. Cohen, S. & Stillman, R.C. pp 111-121. New York: Plenum Medical Book Company
Not provided		Vaswani, S.K. & Criticos, P.S. (1998) Metered dose inhaler: past, present, and future. Ann Allergy Asthma Immunol, 80, 11-9; quiz 19-20
EXAMINER		DATE CONSIDERED 12/17/05

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)



Docket Number (Optional) 02940086AA	Application Number 10/759,280
Applicant(s) Peart et al.	
Filing Date 1-20-04	Group Art Unit 1616

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
JHAA	1	WO 98/24420	6-11-98	PCT				✓

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

JHAA	1	XP008034315, Ungerleider et al. "Cannabis and Cancer Chemotherapy" A comparison of Oral-9-THC and Prochlorperazine; American Cancer Society ppg. 636-345, 1982,
JHAA	2	XP-000961105, Vanchon et al. "Airways to Micro-Aerosolized Delta-9 Tetrahydrocannabinol" 42 Annual Scientific Assembly; September 1976

EXAMINER 	DATE CONSIDERED 12/16/05
--------------	-----------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

